IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

REGENERON PHARMACEUTICALS, INC.,

Plaintiff/Counter-Defendant,

v. **CIVIL NO. 1:22-CV-61 (KLEEH)**

MYLAN PHARMACEUTICALS INC.,

Defendant/Counter-Claimant.

ORDER ON CLAIM CONSTRUCTION

INTRODUCTION

The patents now before the Court with terms requiring construction are: U.S. Patent No. 11,084,865 ("the '865 patent" or the "Formulation Patent") (Dkt. 146, '865 patent); U.S. Patent Nos. 10,888,601 ("the '601 patent") and 11,253,572 ("the '572 patent") (collectively, the "Dosing Patents") (Dkt. 146, '601 patent; Dkt. 146, '572 patent); and U.S. Patent No. 11,104,715 ("the '715 patent" or "the Manufacturing Patent") (Dkt. 146, '715 patent).[1]

[1] Regeneron initially asserted U.S. Patent Nos. 11,053,280, and 11,299,532, (Dkt. 146, MOB at 3, n.3), but has since withdrawn these from the first stage of the litigation.

ORDER ON CLAIM CONSTRUCTION

This Court has examined the disputes over the construction of these claim terms and, on January 24, 2023, held a hearing pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

GENERAL CONCLUSIONS OF LAW

Claim construction is the process by which the Court gives legal effect to the meaning of the claims of the asserted patents. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 321-22 (2015). "It is not an obligatory exercise in redundancy" and is not required where a term's meaning is apparent from the claim language itself or its scope is not disputed. *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). "[S]ome line-drawing problems . . . [are] properly left to the trier of fact." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007).

The Federal Circuit's leading authority on how to construe claims, *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), explains that "the claims of a patent define the invention." *Id.* at 1312 (quotation marks omitted). "[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms" and "the context in which a term is used in the asserted claim can be highly instructive." *Id.* at 1314. This is true for both the claim containing the disputed term itself, as well as all other claims in the patent—whether asserted or unasserted. *Id.*

Indeed, "an independent claim is broader than a claim that depends from it, so if a dependent claim reads on a particular embodiment of the claimed invention, the corresponding independent claim must cover that embodiment as well." *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1380 (Fed. Cir. 2022); *see Phillips*, 415 F.3d at 1314 ("Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.").[2]

Together with the claim language, "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315. The specification may define claim terms "expressly," or it may define them "by implication," *i.e.*, "such that the meaning may be found in or ascertained by a reading of the patent." *Id.* at 1321 (quotation marks omitted). But while the specification serves as a resource to understand the words used in the claims, courts must avoid the "cardinal sin[]" of importing language from the specification into the claims. *Id.* at 1320. Indeed, even if every example described in the specification contains a particular element, such uniformity is *not* enough to justify importing that

[2] An "independent" claim is a standalone claim that contains all the limitations that define an invention, whereas a "dependent" claim refers back to, and incorporates by dependency, a previous independent claim and further limits the claim. *See generally* 37 C.F.R. § 1.75.

element into claims whose plain language does not expressly require it. *See id.* at 1323; *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906-07 (Fed. Cir. 2004); *AstraZeneca AB v. Mylan Pharm. Inc.*, 2022 WL 17178691, at *5-6 (N.D. W. Va. Nov. 23, 2022) ("Dependent claims . . . refer to at least one other claim, include all of the limitations of the claim to which they refer, and specify a further limitation on that claim.").

"[A] court 'should also consider the patent's prosecution history.'" *Phillips*, 415 F.3d at 1317. "Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* To find disavowal of the ordinary meaning of a claim term in view of the specification based on statements in the prosecution history, the Federal Circuit requires that the alleged disavowing actions or statements made during prosecution be "both clear and unmistakable." *CUPP Comput. AS v. Trend Micro Inc.*, 53 F.4th 1376, 1382 (Fed. Cir. 2022).

Where the court "reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." *Teva*, 574 U.S. at 331. However, in

situations where the patent does not provide the meaning for a claim term, a "court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Id.* In those circumstances, the court may "make subsidiary factual findings about that extrinsic evidence." *Id.* at 332. But extrinsic evidence cannot be used to "contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Phillips*, 415 F.3d at 1324. "[A] court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Genuine Enabling Tech. LLC v. Nintendo Co.*, 29 F.4th 1365, 1373 (Fed. Cir. 2022) (quoting *Phillips*, 415 F.3d at 1318); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996) ("[E]xpert testimony ... may not be used to vary or contradict the claim language. Nor may it contradict the import of other parts of the specification." (citation omitted)); *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1332 (Fed. Cir. 2003) ("Yet, Omega submits its expert declarations not to shed light on this field of art, but to rewrite the patent's specification and explicitly provide for the laser splitting

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